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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,565	08/14/2001	Jean-Francois Barault	ETH1475	9842

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EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,565	BARAULT, JEAN-FRANCOIS	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

1. The declaration does not identify the foreign country of residence of the inventor. It is noted that the Citizenship is identified [incorrectly] as *France*, and the Country of Residence is left blank. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. *The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.*

The language should be clear and concise and *should not repeat information given in the title.* It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it does not describe the disclosed invention in enough detail. Applicant should augment the abstract, including that which is new in the art to which the invention pertains. Additionally, the applicant

should avoid using the title of the invention, *Areal Implant,* in the abstract. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities:

3. It is noted that the applicant has failed to include headings for the various sections of the disclosure, including: *Background of the Invention, Brief Summary of Invention,* etc... See MPEP § 608.01(c-h). It is suggested that the applicant correct the application for ease of reading and organizational purposes.

4. It is also noted that the applicant has made a reference to a specific claim within the body of the disclosure [See line 28]. The attempt to incorporate this subject matter into the specification is improper because if the claims are amended during the prosecution of the application, then the claim number in the specification could become incorrect.

5. The claims are objected to because of the following informalities: The present Office practice is to insist that the claims must be the object of a sentence starting with "I (or we) claim," "The invention claimed is" (or the equivalent) [See MPEP § 608.01(m)]. Appropriate correction is required.

6. Claims 5, 7, 9, 10, 11, 13, 15 and 17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 5, 7, 9, 10, 11, 13, 15 and 17 are being treated on the merits as best understood. It is noted that the aforementioned claims which begin "Implant according to one of claims 1 to []" *will be treated as if they are claims depending only upon Claim 1.*

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 9 and 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 9 and 10, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claim 10 is further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by "according to one of claims 1 to 7 *in conjunction with* claim 5 or 6," as the numbers 5 and 6 come sequentially between the numbers 1 and 7.

Claim Rejections - 35 USC § 102

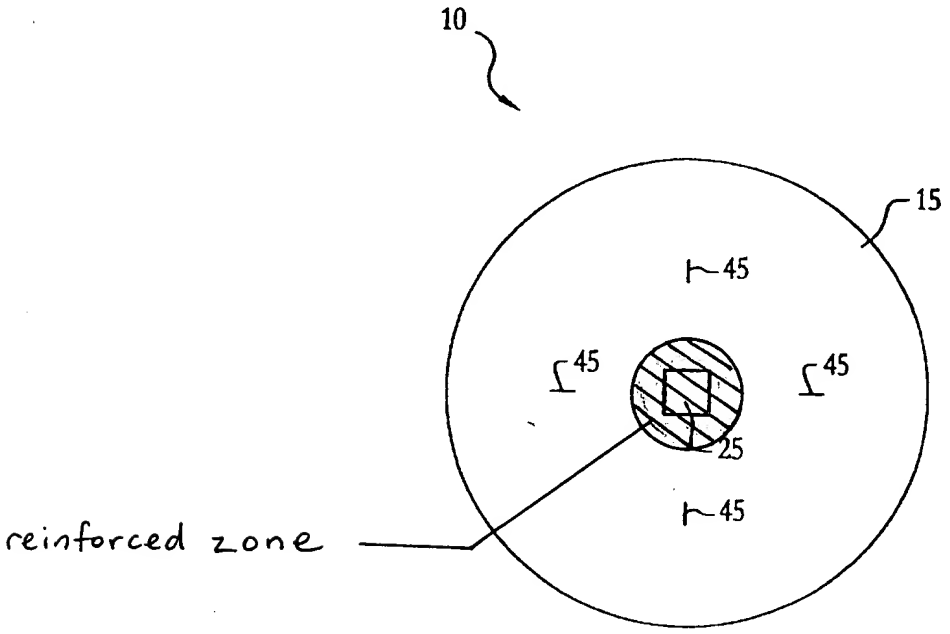
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-5, and 7-12 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,066,776 to Goodwin et al. Regarding Claims 1-3, Goodwin discloses

an areal implant (10) with a mesh-like basic structure (15) and a reinforced zone (labeled in FIG. 2 below) in a central area of the basic structure. The strength of the said reinforced zone decreases towards the peripheral area. Clearly, the reinforced zone will be stronger than the peripheral area of the basic structure, as there is an extra layer of mesh in the reinforced zone [Column 3, lines 41-46]. The reinforced zone (black diagonal lines in FIG. 2 below) has a homogenous central area (25) and a zone (yellow area in FIG. 2 below) of lower strength surrounding the homogenous central area.

FIG. 2



[SOURCE: US Patent No. 6,066,776 to Goodwin et al.]

9. Regarding Claim 4, Goodwin's reinforced zone (black stripes in FIG. 2 above) is made out of mesh and will have a smaller pore size than the peripheral area of the basic structure (15). The homogenous central area (25) in the reinforced zone of Goodwin's implant (10) consists of one mesh laid on top of another piece of mesh [Column 3, lines 41 to 48]. When adding a sheet of fabric on top of another sheet of fabric, inevitably the fibers of the two fabrics will not line up perfectly, i.e. some of the fibers of the upper

fabric will be located above the pores (interstices) of the fabric below, or vice versa. In other words, the pore size will be decreased by the addition of a second sheet of mesh. Therefore, the reinforced zone in Goodwin's mesh will have a smaller pore size than the peripheral area of the basic structure.

10. Regarding Claim 5, Goodwin discloses an implant, containing all of the limitations of Claims 1-4, in which radial reinforcing elements (45) extend from the reinforced zone towards the peripheral edge of the basic structure (15) [Columns 3, lines 66-67; Column 4, lines 1-8; Column 4, lines 24-26].

11. Regarding Claim 7, Goodwin discloses an implant *knitted out of surgical mesh* [Column 3, lines 23-28 in view of *Instructions for Use* by Atrium Medical Corporation, listed on PTO-892] with a weft-knitted or a warp-knitted basic structure. It is well known in the art of making surgical mesh that weft knitting and warp knitting are common ways of making surgical mesh.

12. Regarding Claim 8, Goodwin discloses the claimed invention except the various components of Goodwin's implant are weft-knitted or warp-knitted *separately*, and then *combined* to form one piece. It would have been obvious to one having ordinary skill in the art at the time the invention was made to knit the implant [including the basic structure, the reinforced zone and the homogenous central area] in one piece rather than knitting each part separately and combining them, since it has been held that constructing a formerly piecemeal structure in integral form involves only routine skill in the art.

13. Similarly, regarding Claim 9, Goodwin discloses the claimed invention except that the parts of the reinforced zone of Goodwin's implant are weft-knitted or warp-

knitted *separately*, and then *combined* to form one piece. It would have been obvious to one having ordinary skill in the art at the time the invention was made to knit the reinforced zone in one piece rather than knitting each part of it separately and combining them, since it has been held that constructing a formerly piecemeal structure in integral form involves only routine skill in the art.

14. With respect to Claim 10 [assuming that it is dependent only upon Claim 1, as explained in number 6 above], Goodwin discloses an implant according to Claims 10 and 1, wherein the reinforced zone (15) and the radial reinforcing elements (45) are made in one piece and attached to the separately produced basic structure (35).

15. Regarding Claims 11 and 12, Goodwin discloses an implant according to the applicant's invention, which is comprised of polypropylene [Column 3, lines 23-32 and 44-46], a non-resorbable material.

16. Claims 1-7 are also rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,391,060 to Ory et al. Regarding Claims 1-3, Ory discloses an areal implant (1) with a mesh-like basic structure (1a) and a reinforced zone (inside of red line in below Fig. 4) in a central area of the basic structure. The strength of the said reinforced zone decreases towards the peripheral area. Clearly, the reinforced zone will be stronger than the peripheral area of the basic structure, as there is an extra layer of mesh in the reinforced zone (as shown in Fig. 4 below). The reinforced zone (inside red lines) has a homogenous central area (colored yellow in Fig. 4) and a zone (area between red line and outer edge of panel 9) of lower strength surrounding the homogenous central area.

[SOURCE: US Patent No. 6,391,060 B1 to Ory et al.]

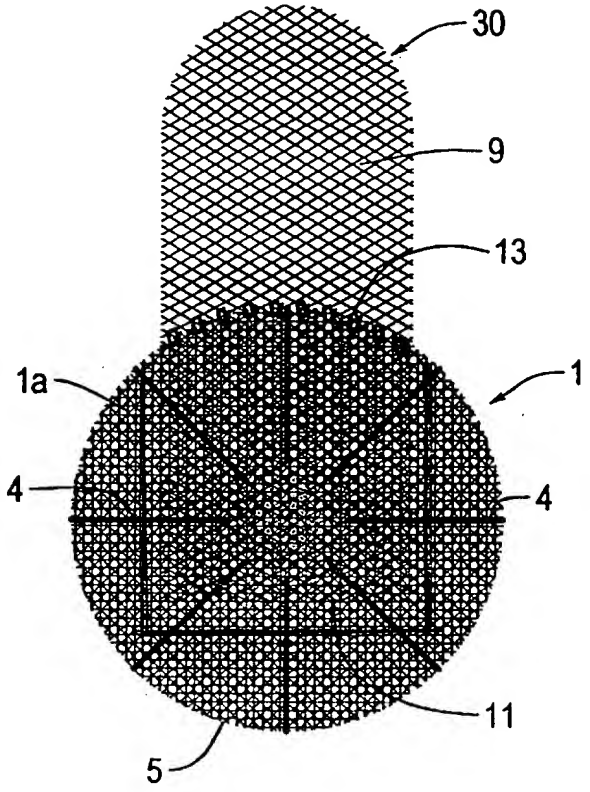


Fig. 4

17. Regarding Claim 4, Ory's reinforced zone (inside of red lines in above Fig. 4) is made out of mesh and will have a smaller pore size than the peripheral area of the basic structure (1a). The homogenous central area (yellow in Fig. 4) in the reinforced zone of Ory's implant (1) consists of one mesh laid on top of another piece of mesh [Column 5, lines 5-17]. When adding a sheet of fabric on top of another sheet of fabric, inevitably the fibers of the two fabrics will not line up perfectly, i.e. some of the fibers of the upper fabric will be located above the pores (interstices) of the fabric below, or vice versa. In other words, the pore size will be decreased by the addition of a second sheet of mesh.

Therefore, the reinforced zone in Ory's mesh will have a smaller pore size than the peripheral area of the basic structure.

18. Regarding Claim 5, Ory discloses an implant, containing all of the limitations of Claims 1-4, in which radial reinforcing elements (4) extend from the reinforced zone towards the peripheral edge of the basic structure (1a) [see Fig. 4].

19. With respect to Claim 6, Ory shows an implant according to the applicant's invention, including at least one radial reinforcing element (4) that is widened in the area of the peripheral edge (5) of the basic structure (1a). The radial reinforcing elements and the discontinuous overstitching (8), as divulged by Ory, are made out of the *same thread* and therefore the overstitching is merely an extension—a widened area—of each radial element [Column 4, lines 17-20 and lines 54-58]. Because the radial reinforcing elements *intersect* the overstitching (8) and the two are made from an identical substance, one would say that the overstitching (8) is merely a widened area of each radial reinforcing element.

20. Regarding Claim 7, Ory discloses an implant with a weft-knitted or a warp-knitted basic structure [Column 3, lines 50-59].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,066,776 to Goodwin et al., in view of U.S. Patent No. 6,162,962 to Hinsch. Regarding Claims 13 and 14, Goodwin discloses a mesh areal implant with a reinforced zone in the middle made out of one of a number of non-resorbable materials. Goodwin does not disclose an implant made out of a specifically resorbable material, as specified in Claims 13 and 14, although Goodwin explains that his implant can be made out of any biomaterial suitable for surgical applications [Column 3, lines 23-32]. One requisite for these biomaterials, as recited by Goodwin, is that they promote tissue ingrowth and attachment to surrounding tissues [Column 3, lines 37-40]. Hinsch discloses an areal implant made out of resorbable materials [Column 11, Claim 8], including poly-p-dioxanone and lactide/glycolide copolymers [Column 11-12, Claim 12].

These resorbable materials are used, as recited by Hinsch, so that the implant will be resorbed by and attach to the tissues around it. Therefore, one would use Hinsch's resorbable materials to facilitate tissue ingrowth in Goodwin's implant. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the specific resorbable materials, as taught by Hinsch, for the non-resorbable materials of Goodwin's implant for the purpose of making the implant be more easily assimilated into the body tissues.

22. Regarding Claims 15-17, Goodwin shows all of the claimed limitations except for the film that is used as a stiffening element in the applicant's implant. The mesh of Goodwin's implant, although it lacks the stiffening film, is meant to promote tissue ingrowth in addition to being of a "sufficient strength and integrity" [Column 3, lines 33-

39]. Hinsch teaches that it is known that one can apply a resorbable "stiffening material" such as a "film" to an implant [Column 3, lines 35-40] in order to cause the implant to be more firm as well as for purpose of facilitating tissue ingrowth [Column 2, lines 55-63]. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply Hinsch's resorbable film as a coating for Goodwin's implant in order to strengthen the implant and to better facilitate tissue ingrowth.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are cited to further show the state of the art with respect to similar areal implants:

U.S. Patent No. 5,725,577 to Saxon discloses an areal implant made out of resorbable and non-resorbable surgical mesh, which has a reinforced zone in a central area of the basic structure.

U.S. Patent No. 5,397,331 to Himpens et al.

U.S. Patent No. 5,879,366 to Shaw et al.

U.S. Patent No. 6,383,201 to Dong

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

bcp
December 27, 2002

KEVIN T. TRUONG
PRIMARY EXAMINER
12/30/02